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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,611	10/16/2001	Toshio Miyata	SHIM010	6955
24353	7590	10/02/2003	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,611	Applicant(s) MIYATA, TOSHIO	
	Examiner Terry A. McKelvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821(d). The application refers to sequences without the use of the correct identifier.

For example, Figure 1 and throughout page 13, etc, the application sets forth sequences without sequence identifiers.

Applicants should carefully review the specification to identify and properly label each sequence that is referred to within the specification, including drawings. Sequences in drawings can be identified with a SEQ ID NO: in the Brief Description of the Drawings for the figure or be present in the figure itself. If one or more sequences are referred to in the specification that are not present in the Sequence Listing, then a new Sequence Listing, a new CRF diskette containing the Sequence Listing and a new statement that the two are the same and includes no new matter must be submitted in order to fully comply with the Sequence Rules.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. Any response

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to this Office Action which fails to meet *all* of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to DNA comprising SEQ ID NO:1, vector comprising the DNA, cell comprising the vector, and the first method of using the DNA comprising a screening a protein that binds to the DNA.

Group II, claim(s) 6-7, drawn to protein isolated that binds to the DNA.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 requires that unity of invention exists only when there is a shared same or corresponding technical feature among

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the claimed inventions. Group I is directed to DNA which is chemically, biologically, functionally, and structurally unrelated to the protein of Group II which binds to the DNA and thus these two groups directed to unrelated compounds lacks the same or corresponding technical feature, especially since as shown below, the DNA is not a contribution over the art.

During a telephone conversation between Laurie Mayes and Karl Bozicevic on 4/18/2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, etc, the use of "DNA comprising ... a part thereof" renders the claims vague and indefinite because

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the metes and bounds of what constitutes a part of the sequence in this context is unclear. A part of a sequence potentially reads on as small as a part as a single nucleotide, which is clearly present in the DNAs of all promoters. It appears that the applicant did not intend for the claims to read on all promoters and thus it is unclear what is intended by the phrase "a part thereof" as claimed.

The metes and bounds of the claimed subject matter of claim 4 is unclear because it is unclear whether applicant is claiming a cell within a subject or the subject itself because the cell reads on being in any environment, including in vivo and hence cannot be removed from the subject

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-2 are rejected under 35 U.S.C. § 101 because the claimed invention is drawn to non-statutory subject matter.

The preamble of the claims recites "A DNA comprising ...". (and A vector comprising the DNA ...". DNA molecules are products of nature that are not statutory subject matter because

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they fail to show the "hand of man" in their construction. Amending the claim to recite "An isolated DNA comprising..." would be remedial. A vector comprising the DNA reads on the natural chromosome carrying the DNA and thus is also a product of nature.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant claims a cell transfected with the vector comprising the claimed DNA. The specification indicates that the DNA can be used for gene therapy and thus the claimed cell can be in a human subject. The claim therefore can be read to include a human being containing the transfected cell because the claim reads on cells making up a portion of a human being. Claims reading on human beings are non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyata et al (indicated as Applicant reference AA1 on the signed IDS).

Miyata et al teach a DNA comprising the promoter of the megsin gene, which because it is taught as being from the same source as the megsin promoter of SEQ ID NO:1 in the instant application, appears to comprise SEQ ID NO:1. The promoter operably linked to the foreign luciferase gene in a vector is also taught, as are cells comprising the vector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata et al (AA1) in view of Miyata et al (AA2) and Chiang (U.S. Patent No. 5,558,999).

Miyata et al (AA1) teach cloning a DNA comprising the promoter of the megsin gene using the cDNA of the gene. The

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resulting DNA, which because it is taught as being from the same source as the megsin promoter of SEQ ID NO:1 in the instant application, appears to inherently comprise SEQ ID NO:1. The promoter operably linked to the foreign luciferase gene in a vector is also taught, as are cells comprising the vector. This reference also teaches: "Analysis of the promoter region of megsin and its regulatory elements will give important insights in the mechanisms responsible for mesangium-predominant gene expression.".

Miyata et al (AA1), depending on the facts of the disclosure that is not set forth in the reference, may not provide an enabling disclosure of the DNA comprising SEQ ID NO:1. Also, this reference does not teach a method of screening for a protein that binds to the promoter DNA comprising SEQ ID NO:1.

Miyata et al (AA2) teaches the nucleotide sequence of cDNA of megsin (Figure 1). This reference also teaches that further studies of the promoter and transcriptional factor of megsin will give an important insight to a mechanism of cell type-dependent gene expression (page 833, column 1).

Chiang teaches that regulatory elements are useful for detecting and isolating transcription factor of the promoter. To detect a transcription factor, a regulatory element is

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contacted with a biological sample suspected of containing a transcription factor, binding between the element and a transcription factor and the step of isolating the transcription factor (which binds the DNA of the element) are accomplished by conventional methods (column 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use either the DNA comprising SEQ ID NO:1 (the megsin promoter) disclosed by Miyata et al (AA1) or use the teachings of Miyata et al (AA2) of the cDNA to isolate the DNA comprising the megsin promoter according to standard techniques and the teachings of Miyata et al (AA1), to isolate the transcription factor(s) that bind to the DNA by contacting a test sample with the DNA using the method taught by Chiang because Miyata et al (AA1) teach the DNA comprising the megsin promoter and/or this reference teaches how to isolate the DNA comprising the megsin promoter based upon the cDNA taught by Miyata et al (AA2) and standard techniques well known in the art, and Chiang teaches that it is within the ordinary skill in the art to identify and isolate transcription factors that bind to promoter DNA.

One would have been motivated to do so for the expected benefit of analyzing the promoter region of megsin and its regulatory elements (which are the binding sites for the

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transcription factors) to give important insights in the mechanisms responsible for mesangium-predominant gene expression as taught by Miyata et al (AA2) and that further studies of the promoter and transcriptional factor of megsin will give an important insight to a mechanism of cell type-dependent gene expression as taught by Miyata et al (AA2). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

September 29, 2003